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| <b>SOP Number:</b> SOP CW AHC 224                                  | <b>SOP Name:</b> IRB Member Addition             |
| <b>Location:</b> *Company-Wide Policies                            | <b>Responsible Department:</b> Research Services |
| <b>Executive Owner:</b><br>Executive Director of Research Services | <b>Original Creation Date:</b> 01/18/2022        |
| <b>Effective Date:</b> 04/04/2022                                  | <b>Review Date:</b> 04/04/2022                   |

- I. **SCOPE:** This standard operating procedure (SOP) applies to the HRPP Administrator.
- II. **PURPOSE:** This procedure establishes the process to add an IRB member to an IRB. This procedure begins when the Organization Official selects a new IRB member. This procedure ends when the individual is not offered IRB membership, or the member has been added and the IRB’s registration has been updated.
- III. **QUALIFIED PERSONNEL:** The HRPP Administrator carries out these procedures.
- IV. **TRAINING:** Not applicable
- V. **SUPPLIES & EQUIPMENT:** Not applicable
- VI. **PROCESS/PROCEDURE:**
  - A. IRB members will be selected based on qualifications, education, experience, and having a positive attitude toward board membership.
  - B. The IRB Executive Chair should normally be an IRB member who is a respected individual with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures.
  - C. IRB vice-chairs:
    1. Discharge the IRB Executive Chair’s responsibilities when the IRB Executive Chair is unable to do so
    2. Discharge the responsibilities assigned by the IRB Executive Chair
    3. Assist in the operation of the IRB
  - D. Begin IRB new member orientation checklist
  - E. Request the individual to complete the IRB application and new member information sheet
  - F. Obtain a copy of the individual’s résumé or curriculum vitae.
  - G. Provide the résumé or curriculum vitae to the Organization Official for review and approval.
  - H. If the Organization Official agrees that the background of the potential member is a good fit with the current membership of the IRB, telephone or in-person interviews will be conducted with an appropriate selection of IRB Executive Chairs, IRB vice-chairs, members, and others as determined necessary. The potential IRB member may also attend and observe an IRB meeting.
  - I. At the completion of the appropriate interviews, the designee will notify the Organization Official that the interviews have been conducted and will summarize the opinions of the interviewers and make a recommendation with regard to having the potential IRB member begin IRB member training.
  - J. Upon successful completion or verification of training, the IRB Executive Chair notifies

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the Organization Official that the individual has completed training and assesses whether they have completed the training in a satisfactory manner to be appointed as a board member.

- K. If the training is satisfactory and the Organization Official agrees, appoint the IRB member and update the IRB roster. If the training is not satisfactory, the IRB Executive Chair and Organization Official will either agree on a plan for additional training or will decline to offer IRB membership to the potential IRB member.
- L. Prepare an appointment letter, have it signed by the IRB Executive Chair, and send to the individual.
- M. Have the individual sign the IRB member agreement.
- N. Obtain information from the individual to complete the IRB roster.
- O. Use HRP-430 WORKSHEET – IRB Composition to evaluate whether the IRB is appropriately constituted.
- P. Revise the membership as needed.
- Q. If the new member is a chair, update the IRB's registration with OHRP at <http://ohrp.cit.nih.gov/efile/> within 90 days.

**VII. DEFINITION(S):** For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

For capitalized designations not defined in this policy, refer to CW AHC 103 Designations in Research.

For abbreviations not defined in this policy, refer to CW AHC 102 Abbreviations in Research.

**VIII. EXCEPTION(S):** See CW AHC 101 Research Oversight

**IX. REFERENCE(S):**

21 CFR §56.106 and §56.107  
45 CFR §46.107 and 45 CFR §46 Subpart E

**X. RELATED DOCUMENT(S) / ATTACHMENT(S):**

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 102 Abbreviations in Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- WORKSHEETS are located on the AdventHealth Research Institute website
  - o HRP-430 WORKSHEET – IRB Composition